INTERNATIONAL STANDARD

ISO 15002

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Flow-metering devices for connection to terminal units of medical gas pipeline systems

Dispositifs de mesure de débit pour raccordement aux prises murales des systèmes de distribution de gaz médicaux

Reference number
ISO 15002:2000(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15002 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Annex A of this International Standard is for information only.

Introduction

This International Standard pays particular attention to:

— safety (mechanical strength, safe relief of excess pressure**,** resistance to ignition);

— gas specificity;

— cleanliness of materials;

— suitability of materials;

— accuracy;

— testing;

— identification;

— information supplied.

Throughout this International Standard, a subclause for which a rationale is provided in annex A is indicated by a boldface capital **R.**

Flow-metering devices for connection to terminal units of medical gas pipeline systems

1 Scope

1.1 This International Standard is applicable to:

— flow-metering devices which are connected, either directly or by means of flexible connecting assemblies, and disconnected by the operator at terminal units of a medical gas pipeline system for measurement and delivery of medical gases;

— flow-metering devices which are connected and disconnected by the operator at gas-specific connection points of devices such as pressure regulators.

1.2 It applies only to flow-metering devices for the following medical gases:

— oxygen,

— nitrous oxide,

— air for breathing,

— carbon dioxide,

— helium,

— xenon,

— specified mixtures of the gases listed above,

— oxygen/nitrous oxide mixture 50/50 (% volume fraction).

1.3 This International Standard is not applicable to electrical or electronic flow-metering devices.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 32, *Gas cylinders for medical use — Marking for identification of content.*

ISO 5359, *Low-pressure hose assemblies for use with medical gases.*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum.*

ISO 11114-3:1997, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere.*

ISO 14971, *Medical devices — Application of risk management to medical devices.*

EN 12218, *Rail systems for supporting medical equipment.*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
DISS connectors
diameter index safety system connectors
range of male and female components intended to maintain gas specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2
flow gauge
gauge which measures pressure differential and which is calibrated in units of flowrate

NOTE The flow gauge indicates flowrate by measuring the pressure upstream of a fixed orifice.

3.3
flowmeter
device that measures and indicates the flow of a specific gas

3.4
flow-metering device
device fitted with an inlet connector and an outlet connector and that incorporates one of the following:

a) a flowmeter and flow control valve

b) a flow gauge and a fixed orifice with a flow control valve

c) multiple fixed orifices with means of selection

3.5
gas-specific
having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only

3.6
gas-specific connection point
that part of the socket which is the receptor for a gas-specific probe

3.7
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.8
medical gas
any gas or mixture of gases intended for administration to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

3.9
medical gas pipeline system
complete system which comprises a source of supply, a pipeline distribution system and terminal units at the points where medical gases or vacuum may be used

3.10
medical gas supply system
medical gas pipeline system or any other installation having no permanent pipeline system but employing a medical gas source complete with pressure regulator(s)

3.11
NIST connectors
non-interchangeable screw-threaded connectors
range of male and female components intended to maintain gas specificity by allocation of a set of different diameters and a left-hand or right-hand screw thread to the mating components for each particular gas

3.12
placing on the market
the first making available, in return for payment or free of charge, of a device other than a device intended for clinical investigation, with a view to distribution and/or use

3.13
probe
male component designed for acceptance by and retention in the socket

3.14
rated inlet pressure
p_1
maximum upstream pressure for which the flow-metering device is designed to operate

NOTE Unless otherwise specified, pressures in this International Standard are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0).

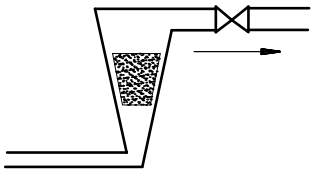
3.15
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.16
socket
that female part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point

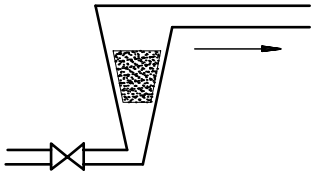
3.17
terminal unit
outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections

4 Arrangement of flow-metering systems and devices

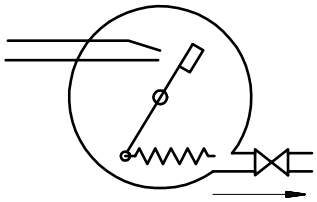
4.1 Typical examples of flow-metering systems are shown in Figure 1.



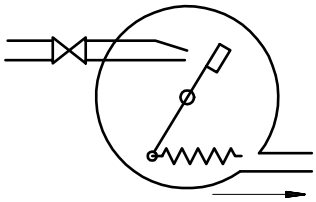
a) Measuring tube with flow control valve downstream



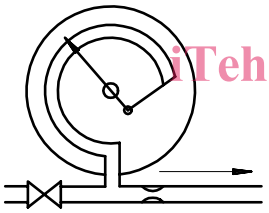
b) Measuring tube with flow control valve upstream



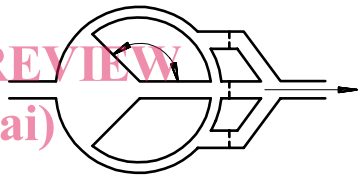
c) Paddle and a fixed orifice with flow control valve downstream



d) Paddle and a fixed orifice with flow control valve upstream



e) Flow gauge and a fixed orifice with flow control valve



f) Multiple fixed orifices with selection knob upstream

Figure 1 — Examples of flow-metering systems

Figure 1 a) shows a system which comprises a vertical measuring tube whose cross-section increases upwards and in which a float is lifted by the action of the gas flow. The float settles at a height which is a function of the flowrate, which is controlled by a flow control valve fitted downstream of the tube.

Figure 1 b) shows the same system as in a) with the flow control valve fitted upstream of the tube.

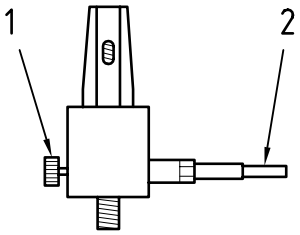
Figure 1 c) shows a system which comprises a paddle connected to a return spring which is located at the outlet of a fixed orifice. The paddle is pushed by the action of the gas flow and settles at a position which is a function of the flowrate, which is controlled by a flow control valve fitted downstream of the orifice.

Figure 1 d) shows the same system as in c) with the flow control valve fitted upstream of the orifice.

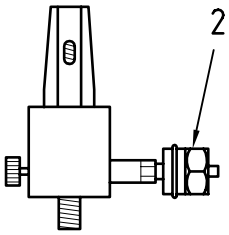
Figure 1 e) shows a system which comprises a pressure gauge measuring the pressure upstream of a fixed orifice. The pressure is a function of the flowrate, which is controlled by a flow control valve fitted upstream of the pressure gauge. The pressure gauge is calibrated in units of flowrate (flow gauge).

Figure 1 f) shows a system which comprises multiple fixed orifices. The change from the "off" position and from one setting to another can be achieved, for example, by turning a knob.

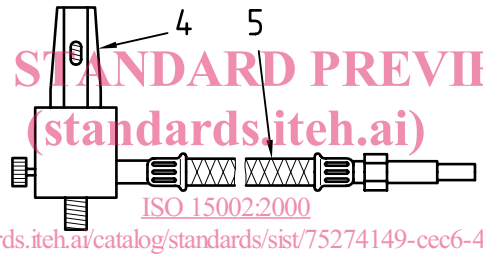
4.2 Typical examples of flow-metering devices are shown in Figure 2.



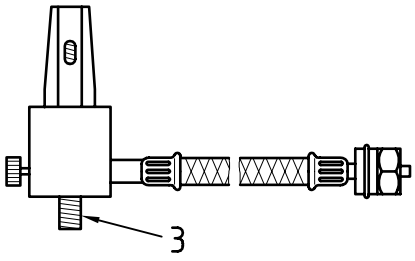
a) Flow-metering device with a probe as inlet connector



b) Flow-metering device with a DISS or NIST nut and nipple as inlet connector



c) Flow-metering device with a hose and a probe as inlet connector



d) Flow-metering device with a hose and a DISS or NIST nut and nipple as inlet connector

Key

1 Flow control valve
2 Inlet connector
3 Outlet connector
4 Measuring tube
5 Hose

Figure 2 — Typical examples of flow-metering devices